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10/540,730	05/03/2006	Nicholas Dale	46309-315846	9069

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EXAMINER
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SAKELARIS, SALLY A

ART UNIT	PAPER NUMBER
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1773

NOTIFICATION DATE	DELIVERY MODE
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03/23/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/540,730	<b>Applicant(s)</b> DALE ET AL.	
	<b>Examiner</b> SALLY A. SAKELARIS	<b>Art Unit</b> 1773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26-29, 31-49, 51 and 54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-29, 31-49, 51, and 54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Response to Amendment**

The amendment filed 1/26/2011 has been received and considered for examination.

Claims 26-29, 31-49, 51, and 54 remain pending.

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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1. Claims 26, 27, 31-33, 38, 39, 51 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Havens et al. (US 6306348).

With regard to claims 26 and 27, Havens et al. teach a method of, and a device created by depositing an inorganic permeation layer consisting of a sol-gel onto a micro-electronic device for molecular biological reactions (Abstract). Havens et al. further teach that their microelectrodes can be of any shape, preferably round, square, or rectangular. Havens further teaches that the size of their addressable micro-electrodes to be of any size but preferably to range from sub-micron ( $\sim 0.5\mu\text{m}$ ) to several centimeters, with  $5\mu\text{m}$  to  $100\mu\text{m}$  being the most preferred size range for devices fabricated using microlithographic techniques (Col. 5 lines 5-19). Additionally, Havens et al. teach that each micro-location (32) is  $\sim 50\mu\text{m}$  square with  $50\mu\text{m}$  spacing between neighboring locations (Col. 7 lines 1-11). Therefore, Havens et al. teach a microelectrode that is less than 10 mm long and from about 10 to  $50\mu\text{m}$  in width.

Havens et al. does not teach a microelectrode with a diameter of about 10 to  $50\mu\text{m}$ .

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have been motivated by Havens et al's teachings summarized above that provided an expectation of success by using any shape or size microelectrode to be coated, wherein this microelectrode/device has a diameter instead of a width of the same dimension, i.e., about 10 to  $50\mu\text{m}$ .

With regard to claims 31-33, Havens et al. teach that their microelectrodes comprise a sol gel layer that can readily bind a fluorescently labeled capture probe (i.e., biological material, nucleic acid, or oligonucleotide) (Figure 9, Col. 9, lines 53-65).

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With regard to claims 38 and 39, Havens et al. teach that their sol gel permeation layer comprises a partially hydrolyzed metal alkoxide solution in addition to their tetraethyl orthosilicate and the remaining contents seen in the table of Col. 8 lines 55-68).

With regard to claims 51 and 54, Havens further teaches that the size of their addressable micro-electrodes to be of any size but preferably to range from sub-micron ( $\sim 0.5\mu\text{m}$ ) to several centimeters, with  $5\mu\text{m}$  to  $100\mu\text{m}$  being the most preferred size range for devices fabricated using microlithographic techniques (Col. 5 lines 5-19).

2. Claims 28-29, 34-37, 40-44, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Havens et al. (US 6306348) in view of Zhang et al. (Analytica Chimica Acta 388 (1999) 71-78).

The teachings of Havens et al. can be seen above.

With regard to claim 28, Havens et al. do not teach that the sol-gel on their microelectrode comprises mercaptan-containing silane.

With regard to claim 28, Zhang et al. teach a sol gel coated microelectrode. Furthermore, while it is maintained that the limitations of a product by process claim are fully met by minimally teaching the claimed structure, Zhang et al. teach a device where the sol-gel was obtained through a reaction comprising 3-Mercaptopropyltrimethoxysilane (MPTMS) (Page 72 right hand side).

It would have been obvious at the time the invention was made to a person of ordinary skill in the art to have used the MPTMS as taught by Zhang et al. within the Sol-gel of Havens et al. as Zhang provides the motivation to do so in that first their preparation was well known in the

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art (as noted in the reference by a literature citation) but second because Zhang et al. provide that it is a method for attaching biologically active species to functionalize an electronic sensor that provides advantages such as physical rigidity, negligible swelling in both aqueous and organic solution; chemical inertness; high biodegradational, photochemical, and thermal stability and finally excellent optical transparency (Pg. 71 bottom right side).

With regard to claim 29, Havens et al. do not teach a potentiometer.

With regard to claim 29, Zhang et al. teach a BAS100B/W potentiometer (Pg. 72 right hand side).

It would have been obvious at the time the invention was made to a person of ordinary skill in the art to have used the potentiometer as taught by Zhang et al. within the device of Havens et al. as its obvious to combine prior art elements according to known methods to yield predictable results. In this particular case, the potentiometer is an instrument that is well known in the art to be used to measure a response of an electrode or series of electrodes.

With regard to claims 34-37, Havens et al. does not teach an enzyme included in their Sol-gel.

With regard to claims 34 and 35, Zhang teaches that his biosensor is comprised of a biological material such as Horse Radish Peroxidase (HRP) for example, that is capable of functioning and being used as claimed.

It would have been obvious at the time the invention was made to a person of ordinary skill in the art to have used an enzyme like HRP as taught by Zhang et al. within the Sol-gel of Havens et al. as HRP provides a fluorescent signature making optical detection possible and generally since such a sensor resulted in the provision of several advantages such as physical

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rigidity, negligible swelling in both aqueous and organic solution; chemical inertness; high biodegradational, photochemical, and thermal stability and finally excellent optical transparency (Pg. 71 bottom right side).

With regard to claims 36 and 37, Zhang teaches that his biosensor is comprised of a biological material such as Horse Radish Peroxidase (HRP) for example and that sol-gel coating is a versatile technique that has been extensively applied in the immobilization of enzyme, antigen, and antibody, especially in the biosensor field (Page 71, right hand side).

With regard to claims 36 and 37 Zhang does not teach using two or more enzymes in their biosensor.

With regard to claims 36 and 37, addition of a second enzyme to the sensor, would have been obvious to one having ordinary skill in the art at the time the invention was made. Mere **duplication of parts** has no patentable significance unless a new and unexpected result is produced. In re Harza, 124 USPQ 378, 380 (CCPA 1960). Further, it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8. Additional enzymes would have been added to the biosensor of Havens et al. in view of Zhang by a skilled artisan who was motivated to create a biosensor capable of various different detection methods and applicability. Biosensor capable of detecting various different elements are well known in the art.

With regard to claims 40-44 and 47, Havens et al. do not teach MPTMS or MeTMOS to be included in their Sol-gel.

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Zhang et al. teach their sol-gel was obtained through a reaction comprising silane coupling reagents such as 3-Mercaptopropyltrimethoxysilane (MPTMS) and therefore contains an alkoxysilane and furthermore a MeTMOS (Pg. 72, right side).

It would have been obvious at the time the invention was made to a person of ordinary skill in the art to have used the MPTMS and TMOS as taught by Zhang et al. within the device of Havens et al. as its obvious to combine prior art elements according to known methods to yield predictable results. Furthermore, Zhang et al. provides the motivation in that the sensor he teaches generally resulted in the provision of several advantages such as physical rigidity, negligible swelling in both aqueous and organic solution; chemical inertness; high biodegradational, photochemical, and thermal stability and finally excellent optical transparency (Pg. 71 bottom right side).

3. Claims 45, 46, 48, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Havens et al. (US 6306348) in view of Zhang et al. (Analytica Chimica Acta 388 (1999) 71-78 and in further view of Collinson et al. (Analytica Chimica Acta 397 (1999) 113-121).

The teachings of Havens et al. in view of Zhang can be seen above.

Havens et al. in view of Zhang does not teach the use of APTEOS as one of their silane coupling agents.

Collinson et al. teach the organic modification of silicates from APTEOS. Among other agents, APTEOS was hydrolyzed and copolymerized and the resultant hybrid sol spin cast on the surface of a glassy carbon electrode (Abstract).



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It would have been obvious to one of ordinary skill in the art at the time the invention was made to use agents comprising APTEOS in the creation of a hybrid sol of Havens in view of Zhang's substrate for the expected benefit as taught by Collinson et al. that such films "showed significantly faster ion-exchange relative to films prepared with either TMOS or MTMOS, presumably due to a more open silicate framework"(Abstract).

### **Response to Arguments**

Applicant's arguments with respect to claims 26-29, 31-49, 51, and 54 have been considered but are moot in view of the new ground(s) of rejection.

### **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to SALLY A. SAKELARIS whose telephone number is (571)272-6297. The examiner can normally be reached on Monday-Friday 8-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 5712721267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sally A Sakelaris/  
Examiner, Art Unit 1773  
3/15/2011